

REMARKS

The document is submitted in reply to the Office Action dated March 18, 2010 ("Office Action"). Applicants have amended claim 1 to more particularly point out the subject matter that they deem to be their invention and added new claims 46-50. Support for the amendments and new claims can be found in the Specification and original claims. Examples of the support are listed in the table below. No new matter is added.

Table. Support for Amendments and New Claims

Amendments or New Claims	Support in Specification or original claims
Claim 1 "eliciting an immune response specific to the antigen to prevent or treat an infection or disorder"	page 6, lines 20-27; original claims 17-20
Claim 46	page 5, third paragraph; page 7, first paragraph; original claims 17-20
Claim 47 "an antigen obtain from a pathogen" "a self-antigen" "a tumor specific antigen"	page 7, first paragraph page 7, second paragraph page 7, first paragraph
Claim 48 "a parasite" "fungus" "virus" "bacteria" "other micro-organism"	page 5, third paragraph page 5, third paragraph page 5, third paragraph page 7, first paragraph page 7, first paragraph
Claim 49	page 6, last paragraph
Claim 50	pages 27-28, carryover paragraph

Upon entry of the proposed amendments, claims 2-6, 10, 11, 13, 15-18, 21-26, 28-38, and 40-50 will be pending. Among them, claims 17, 18, 21-26, and 28-38 have been withdrawn from consideration and claims 2-6, 10, 11, 13, 15, 16 and 40-50 will be under examination. Applicants respectfully request that the Examiner reconsider this application in view of the following remarks.

35 U.S.C. § 102 (a) Rejections

The Examiner rejects claims 2-5, 10-11, 13, and 15-16 for lack of novelty over Hayball *et al.* Immunology and Cell Biology (2000) 78, 13-19 ("Hayball") as evidenced

by Bannantine *et al.* Journal of Clinical Microbiology (2004) p106-114 (“Bannantine”) and Invitrogen product information 2008. See page 2, items 7 and 8. In the sole interest of moving this case forward, Applicants have amended independent claim 2 and will discuss this claim first.

Claim 2, as amended, is drawn to a conjugate which comprises an antigen-presenting cell (APC) targeting molecule coupled to an antigen. The APC-targeting molecule is a mutated superantigen having one or more mutations only in its T cell binding site as compared to its wild-type counterpart; the conjugate is capable of binding to a Class II MHC molecule and eliciting an immune response specific to the antigen to prevent or treat an infection or disorder. According to the Examiner, Hayball teaches a “superantigen ... fused to polyhistidine.” As such, she concludes that “[t]he superantigen/His fusion protein of Hayball *et al.* is structurally identical to that of [previously presented claim 2]” and therefore “anticipates the invention [of claim 2].” See the Office Action, page 3, first and second paragraphs. Given her conclusion, it appears to be the Examiner’s position that the “polyhistidine” described in Hayball is equivalent to “antigen” as recited in claim 2, as both are coupled or fused to a superantigen.

Applicants would like to point out that the “polyhistidine” described in Hayball is not equivalent to “antigen” as recited in claim 2. More specifically, the conjugate of amended claim 2 is designed for “eliciting an immune response specific to the antigen to prevent or treat an infection or disorder.” It follows that the antigen must have certain significance to the infection or disorder. For example, as disclosed in the Specification, the antigen can be, or resemble, a protein or other molecules that is present in a pathogen or that otherwise mediates a disease. See, e.g., Examples 11-15 at pages 26-30 of the Specification. As a result, the antigen allows a targeted immune response to be elicited against the disease once the claimed conjugate is administered to a subject.

In contrast, the “polyhistidine” described in Hayball does not have any significance to an infection or a disorder. Indeed, it was well known in the art that polyhistidine is a tag that merely aids the purification of an expressed fusion protein. It is

of no functional significance to the fusion protein and is not known to have any antigenic relevance to a disease or infection. This is further evidenced by Bannantine, a secondary reference cited by the Examiner. As pointed out by the Examiner, Bannantine teaches that “polyhistine is non-immunogenic.” See the Office Action, page 3, lines 10-11.

In view of the above amendment and remarks, Applicants submit that the “polyhistidine” described in Hayball is not equivalent to “antigen” as recited in claim 2. Thus, amended claim 2 is novel over Hayball as evidenced by Bannantine and Invitrogen product information 2008. Claims 3-6, 10, 11, 13, 15, 16 and 40-49 depend from claim 2 directly or indirectly. For at least the same reasons, they are also novel over the cited references.

Request for Rejoinder

Claims 17, 21, and 26 are drawn to methods for preparing or using the conjugate of claim 2. Claims 17, 21, and 26, and their dependent claims (i.e., claims 18, 22-25, and 28-38) were previously withdrawn from further consideration for covering non-elected subject matter. These withdrawn method claims have been amended to include all the limitations of allowable product claim 2. Applicants request rejoinder of the withdrawn method claims pursuant to MPEP § 821.04(b).

CONCLUSION

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

The Petition for Extension of Time fee in the amount of \$555 is being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account

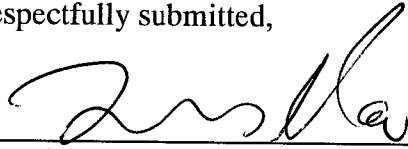
Applicants : John David Fraser *et al.*
Serial No. : 10/006,797
Filed : December 4, 2001
Page : 11 of 11

Attorney Docket No.: 55503-002001
Client Ref. No.: MK504269-003

authorization. Please apply any other charges or credits to Deposit Account No. 50-4189, referencing Attorney Docket No. 55503-002001.

Respectfully submitted,

Date: 9-14-2010



Jianming Hao, Ph.D., J.D.
Reg. No. 54,694

Customer No. 69713
Occhiuti Rohlicek & Tsao LLP
10 Fawcett Street
Cambridge, MA 02138
Telephone: (617) 500-2512
Facsimile: (617) 500-2499
165658.doc